



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/892,993

06/27/2001

Kelly R. Brown

ETH-1567

3764

27614

7590

12/08/2009

MCCARTER & ENGLISH, LLP NEWARK  
FOUR GATEWAY CENTER  
100 MULBERRY STREET  
NEWARK, NJ 07102

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/892,993	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26 and 46-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 46-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

The examiner acknowledges receipt of amendment and remarks filed 8/25/2009. New claim 53 is added. Claims 26, 46 and 47 are amended. Claims 26 and 46-53 are pending.

### ***Response to Arguments***

***Previous rejections and objections that are not reiterated herein are withdrawn.***

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26 and 46-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

4. Claims 26, 47 and 53 recite that the scaffold has "plurality of substantial parallel layers." Applicant has not pointed to portions of the specification that supports this new limitation and the examiner does not find the support in the specification as filed. While plurality of pores is

Art Unit: 1618

present both the ceramic and polymer phases, even the figures supports at best three layers, a polymer layer, a ceramic layer and the interphase layer between the ceramic and polymer layers. Three layers do not provide antecedent support for the many/plurality of layers recited in amended claims 26 and 47 and new claim 453. Since plurality of layers was not envisioned by the originally filed specification, the recitation is new.

5. The above rejection may be overcome by deleting limitations that are new to the original invention.

6. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. It is unclear what it means by "plurality of said plurality of extensions" in second to the last line of claim 46.

### ***Response to Arguments***

8. Applicant's arguments filed 8/25/09 have been fully considered but they are not persuasive.

9. Applicant argues that the two layers represent plurality of layers. The examiner disagrees. Two or three layers do not represent plurality of layers.

10. Applicant has cited *ResQNet.com Inc. v. Lansa Inc.*, 346 F3d 1374 (CAFC 2003).

However, in that case the court held that the specification properly confirms the meaning of the claims. However, in the present case, the specification does not provide or confirm the meaning of the "plurality of substantially parallel layers." Three or two layers do not represent plurality of substantially parallel layers. Amending the specification to include plurality of substantially parallel layers will introduce new matter into the specification and violate the requirements of 35

Art Unit: 1618

USC 132(a). Furthermore, amending the claims to recite at least two or two or more will introduce new matter into the claims and raise rejections under 35 USC 112, 1<sup>st</sup> paragraph.

11. With regards to the rejection under 35 USC 112, 2<sup>nd</sup>, applicant's explanation does not clarify "plurality of said plurality of extensions" found in second to the last line of claim 46 and the claim remains unclear.

12. With regards to applicants proposal to amend claim 46 to say at least two or two or more, it is noted that such an amendment will introduce new matter into the claim and raise rejection under 35 USC 112, 2<sup>nd</sup>.

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claim 53 is rejected under 35 U.S.C. 102(a) as being anticipated by Niederauer et al.

("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000).

15. Claim 53 is a product by process claim.

16. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

Art Unit: 1618

unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

17. The patentability of present claim 53 is based on the product itself and in this case to the scaffold. Therefore, the scaffold of Niederauer anticipates the claimed scaffold.

### ***Response to Arguments***

18. Applicant's arguments filed 8/25/09 have been fully considered but they are not persuasive.

19. Applicant holds the opinion that that the product formed by the recited process is free of the art. However, as described above, the patentability of a product by process claim is based on the product itself. Applicant has the burden of showing that the prior art scaffold is not the same as the claimed scaffold. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.

### ***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1618

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (US 6,376,573) in view of Ries et al. (US 4,623,553) for reasons of record with minor modification.

23. White teaches porous ceramic biomaterial in which polylactic acid or collagen is allowed to fill the pores of the ceramic (abstract). The starting porous ceramic (abstract; column 3, lines 5-22; column 4, lines 7-56) meets the requirement of claim 46 where a porous ceramic body is provided. The prepared gelatin solution (column 6, line 62, 63; column 8, lines 18-42) meets preparation of the polymer solution of claim 48); allowing the polymer solution to wick into the pores of the ceramic (Examples I-VI) meets the requirement for the polymer to infuse into the pores in claim 46. The wicking of the polymer solution into the pores of the ceramic is a mechanical or physical process and polymer and the ceramic interlock after the infusion. Furthermore, the polymer infused into the polymer pores is at a given depth and meets that limitation in the claim noting that no specific depth in centimeters or millimeters is claimed.

Art Unit: 1618

24. While the solvent in the case of Example I is removed in the vacuum oven, White does not teach lyophilization of the polymer infused ceramic, lyophilization is a known process for drying samples. For example, Ries dries ceramic products by lyophilization (see claim 1) . Therefore, taking the teachings of White and Ries, one having ordinary skill in the art would dry reasonably expect that the polymer infused ceramic can either be dried in vacuum oven or can be dried by lyophilization since the two process would equivalently produce dried product.

***Response to Arguments***

25. Applicant's arguments filed 8/25/09 have been fully considered but they are not persuasive.

26. Applicant argues that White teaches away from the invention by disclosing that the micropores of the hydroxyapatite are too small to support in growth of bone cells and accordingly suggest that those micropores are filled with collagen, which will inhibit cell in-growth; and also that the presence of collagen in the micropores makes bone in-growth inaccessible. Applicant supports this position by citing col. 2, lines 46-49 and column 4, lines 49-52.

27. The examiner disagrees. In col. 2, lines 46-49, White talks about the prior art. In column 2, lines 52-57, White specifically proposes ways to overcome the limitation of the prior art by proposing to maintain macroporosity for bone growth.

28. Also, column 4, lines 49-52, discloses leaving macroporous passageway to allow for substantial bone tissue growth into the unfilled macroporous passageway.

29. Therefore, contrary to applicant's arguments, White anticipates bone in-growth into macroporous passageways.



Art Unit: 1618

30. Applicant further argues that that combination of Ries would not provide the features of the claimed invention because, neither reference discloses forming a scaffold with a layer of polymer on a ceramic body with an interlocking interface of polymer extensions extending into the macropores of the ceramic body.

31. The examiner disagrees. It is clear that one of the goals of White is to encourage bone in-growth into macroporous passageway (see col. 2, lines 51 and 52 and col. 4, lines 51 and 52.

32. The starting porous ceramic (abstract; column 3, lines 5-22; column 4, lines 7-56) meets the requirement of claim 46 where a porous ceramic body is provided. The prepared gelatin solution (column 6, line 62, 63; column 8, lines 18-42) meets preparation of the polymer solution of claim 48); allowing the polymer solution to wick into the pores of the ceramic (Examples I-VI) meets the requirement for the polymer to infuse into the pores in claim 46. The wicking of the polymer solution into the pores of the ceramic is a mechanical or physical process and polymer and the ceramic interlock after the infusion. Furthermore, the polymer infused into the polymer pores is at a given depth and meets that limitation in the claim noting that no specific depth in centimeters or millimeters is claimed. Ries is relied upon for teaching lyophilization not for an interlocking interface.

33. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000) for reasons of record with minor modification.

34. Claim 26 is a method of repairing a defect area at the gradient junction of cartilaginous tissue and bony tissues by using a composite laminate scaffold.

Art Unit: 1618

35. Niederauer describes the use of biodegradable multiphase scaffold for repair of articular cartilage (abstract); the multiphase scaffold comprises polymer and ceramic phases (Table 1 and 3<sup>rd</sup> and 4<sup>th</sup> full paragraphs, left column of page 2563) meeting the claimed scaffold having a ceramic and polymer phase; the phases are glued together using a solvent (page 2563, first three lines of text in right column) representing the discrete phases of scaffold of the claim 26. The construct of Niederauer is porous (see left column of page 2563) so that the porous nature of the polymer and ceramic phases are met and the also meets the plurality of pores claimed. Since the ceramic and polymer phases are placed next to each other, the phases would inherently communicate or interact at the interphase/junction region of the ceramic and polymer phases so that interaction between the phases is met; boring a receptacle space at the gradient junction of the site of injury as recited in claim 26 reads on the experimental design of Niederauer where defect sites are made in the right and left stifles and bilateral arthrotomies performed to place the implants (paragraph 2.4 at page 2564); the scaffold is implanted into the prepared knees. The interphase region between the polymer phase and the ceramic phase as claimed is the same region in Niederauer that is between the polymer phase and the ceramic phase. Niederauer is silent on placing the ceramic phase next to the bony tissue and placing the polymer phase next to the cartilage tissue. However, it is known in the art that ceramics closely resemble constituents of natural bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Niederauer to repair articular cartilage by placing the ceramic phase of the scaffold next to the bony tissue since the ceramic material closely resembles the bony tissue so that the bony tissue would grow into the ceramic tissue during the repair process.

Art Unit: 1618

36. The three dimensional nature, the staking of layers along the first dimension of the scaffold and the recitation of the first and fourth surfaces having an area approximating the cross sectional area of the scaffold taken at perpendicular orientation to the first dimension are all inherent to the scaffold.

37. Claim 47 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in *Biomaterials*, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000) for reasons of record with minor modification.

38. Niederauer describes the use of biodegradable multiphase scaffold for repair of articular cartilage (abstract); the multiphase scaffold comprises polymer and ceramic phases (Table 1 and 3<sup>rd</sup> and 4<sup>th</sup> full paragraphs, left column of page 2563) meeting the claimed scaffold having a ceramic and polymer phase; the phases are glued together using a solvent (page 2563, first three lines of text in right column) representing the discrete phases of scaffold of the claim 47. The construct of Niederauer is porous (see left column of page 2563) so that the porous nature of the polymer and ceramic phases are met and the also meets the plurality of pores claimed. Since the ceramic and polymer phases are placed next to each other, the phases would inherently communicate or interact at the interphase/junction region of the ceramic and polymer phases so that interaction between the phases is met; the face of the polymer that is in direct communication with the ceramic phase is distal to the face that is not communicating with the ceramic; by the same token, the face of the ceramic that is communicating with the polymer phase distal to the other face removed from the polymer phase; the scaffold is implanted into the prepared knees. Because the solvent dissolves the interphase region between the polymer and the ceramic, the polymer extends into the pores of the ceramic and the ceramic extends into the

Art Unit: 1618

pores of the polymer so that at the end, when the solvent has evaporated and the region is settled, there would be multiple extensions of polymer and ceramic into the pores of ceramic and polymer respectively to provide interaction that is representative of mechanical interlock between the ceramic and polymer phase because the interaction is physical, and not chemical. The composite of claim 47 reads on the composite of Niederauer. The difference between claim 47 and Niederauer is that Niederauer does not specifically state that the polymer and ceramic phases are communicating via an interphase region. However, since the polymer and ceramic phases are attached to each other, the polymer and ceramic phases are communicating through that region of interaction. However, in the alternate, it would be reasonable to expect that the polymer and ceramic phases are interacting through the region of attachment where it is also reasonable expected that the polymer phase and the ceramic phase having been in contact with the solvent would dissolve at the interphase and undergo migration, the polymer into the ceramic and the ceramic into the polymer into the polymer. The interphase region between the polymer phase and the ceramic phase as claimed is the same region in Niederauer that is between the polymer phase and the ceramic phase. It therefore flows that the polymer and ceramic are interacting at the interphase region and are mechanically interlocked in view of the extensions into the polymer and into the ceramic.

39. The three dimensional nature, the staking of layers along the first dimension of the scaffold and the recitation of the first and fourth surfaces having an area approximating the cross sectional area of the scaffold taken at perpendicular orientation to the first dimension are all inherent to the scaffold.

***Response to Arguments***

40. Applicant's arguments filed 8/25/09 have been fully considered but they are not persuasive.

41. Applicant appears to suggest that the separate rejections of claims 26 and 47 should be combined because the amendment to the claims has drawn the claims closer in scope. However, the rejections are still separated, but the response to applicant's arguments regarding claims 26 and 47 are addressed below.

42. Applicant argues that Niederauer discloses laminated scaffold having cartilage and bone phases. The cartilage phase is composed of mixtures of polymer and the polymers potentially include polyglycolic fibers. The bone phase includes mixtures of polymers with or without polyglycolic acid or mixtures of polymer with non-polymeric inclusions namely: bioglass having sizes of 53-90 mm or medical grade calcium sulfate particle. Applicant then said that the ceramic powder-polymer composite of the type in Niederauer have the disadvantage that that the presence of binding polymeric material prevents direct contact between the bioceramic and bone tissue according to Tomalia at column 2, lines 8-27.

43. While it may be so that there is lack of contact between the bioceramic and the tissue in view of the presence of polymeric material, the rejections have not cited Tomalia as a secondary reference. However, col. 2, lines 8-27 is background information that describes the disadvantages of bioceramic polymer composite. But, this is not the story of Tomalia. Rather in col. 3, lines 56-65, Tomalia clearly describes the invention where it was unexpected that in the bioceramics and bioceramic composite structures of Tomalia, the problematic properties and weaknesses of the known material were eliminated yielding structures that have surprisingly good mechanical stiffness, toughness, strength and that the composition is easily handled during

Art Unit: 1618

operation. In col. 4, lines 1-17, Tomalia discloses that tissues surrounding the composite begin to grow immediately after the operation to direct contact with the bioceramic component or into it through the open porosity of the material, that after the resorption of material component, the tissues in contact with the material component can grow. Therefore, the story is that direct contact and growth of bone is achieved in Tomalia and Tomalia's work overcame the limitations of the prior art described in the background.

44. Claims 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in *Biomaterials*, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000) in view of Tomalia et al. (US 5,084,051) for reasons of record with minor modification.

45. Niederauer is described above to anticipate or render obvious claim 47. Niederauer scaffolds are loaded with cells (second full paragraph, left column of page 2562) meeting claim 50 and inclusion of growth factors, perichondrial cells in the scaffold (see introduction and second full paragraph, left column of page 2562) meet claim 49. Since the polymer and ceramic layers are biodegradable in Niederauer, claim 51 is met. Regarding claim 52, the scaffold exhibiting compositional transition in the interphase region is intrinsic, but because the ceramic and the polymer layers interact at the interphase region where the dissolved ceramic migrates into the pores of the polymer phase and the dissolved polymer migrates into the pores of the ceramic phase, a mechanical interlock ensues at the end of the migration after the solvent dries so that claim 52 is met.

46. Niederauer does not teach the limitations of claim 48 requiring mechanical reinforcement. But Tomalia discloses that porous polymer component of a biocomposite can be

Art Unit: 1618

reinforced with fabric or with parallel or randomly oriented fibers and the reinforcement material can be made of resorbable materials such as polymer, copolymer, polymer mixture and/or ceramic material, fabric, non-woven gauches and short fibers (column 8, lines 57-67 and column 9, lines 45-52).

47. Therefore, taking the teachings of Niederauer in view of Tomalia, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that including fibers or felts or non-woven fabric or short fibers into the porous composite of Niederauer would reinforce the porous composite.

48. For claim 47, the three dimensional nature, the staking of layers along the first dimension of the scaffold and the recitation of the first and fourth surfaces having an area approximating the cross sectional area of the scaffold taken at perpendicular orientation to the first dimension are all inherent to the scaffold.

### ***Response to Arguments***

49. Applicant's arguments filed 8/25/2009 have been fully considered but they are not persuasive.

50. Applicant indicates that the examiner has not described how Niederauer renders obvious claim 47. The examiner disagrees with this characterization. Paragraph 19 and 20 of the office action of 5/29/09 describes Niederauer to anticipate or in the alternate render obvious claim 47. Also paragraph 22 of the office action of 5/29/09 states: "Niederauer is described above to anticipate or render obvious claim 47." Therefore, the examiner addressed claim 47.

51. Applicant relies on the previous arguments presented against the rejections of claims 26 and 47 and states that the amendment of claim 47 distinguishes the claim over Niederauer and that the claims depending from claim 47 are thus patentable based on their dependency.

52. The examiner disagrees. The response provided in paragraphs [42] and [43] above are incorporated herein to address applicant's reference to previous arguments.

53. No claim is allowed.

54. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

55. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

56. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1618

57. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/  
Primary Examiner, Art Unit 1618